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10/575,249	04/10/2006	Pierre-Etienne Chabrier de Lassauniere	58767.000012	7098

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EXAMINER	
ANDERSON, REBECCA L	

ART UNIT	PAPER NUMBER
1626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,249	CHABRIER DE LASSAUNIERE ET AL.	
	Examiner	Art Unit	
	REBECCA L. ANDERSON	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *2 and 6-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-5 and 11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10089993 and 10915001.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are currently pending in the instant application. Claims 2 and 6-10 are withdrawn as being for non-elected subject matter. Claims 1, 3-5 and 11-15 are rejected.

Response to Amendment and Arguments

Applicants' amendment and arguments filed 14 February 2008 have been considered and entered into the instant application.

Applicants' amendment has overcome the objection to the claims as containing non-elected subject matter.

US Patent Application No. 10/681,002 has been expressly abandoned and therefore the provisional obviousness type double patenting rejection is withdrawn. However, applicants' instant claims 1, 4 and 5 are now provisionally rejected under obviousness type double patenting over US Patent Application No. 12/001439, a divisonal of US Patent Application No. 10/681,002.

In regards to the priority date for the pending claims, Applicant's arguments filed 14 February 2008 have been fully considered but they are not persuasive. Specifically, applicant argues that virtually all of the compounds find literal support in the original claims of 10/681,002 or 10/915,001. This argument is not persuasive and the claims do not receive benefit of priority back to 10/681,002 or 10/915,001 since some of the species claimed do not find support in 10/681,002 or 10/915,001. Applicant provided a table on pages 9-11 of the remarks to show support for the species of the claims in 10/681,002 and 10/915,001, however, the 6th, 7th, 11th, 14th, 17th-21st, 24th and 28th

listed compounds of the table do not find support in 10/915,001 as the examples in the prior application are to HCL salts. The 8th, 10th, 13th, 25th and 26th compounds listed in the table do not find support in 10/681,002 or 10/915,001 as the examples in the prior applications are to HCl salts. The 12th listed compound does not find support as only the HCl salt is found in 10/915,001 and paragraph [2553] does not disclose the 12th listed compound. The 15th, 22nd and 23rd listed compounds are not found anywhere in 10/915,001. The 16th listed compound is not found anywhere in 10/681,002 as example [2528] does not disclose the 16th listed compound. The 28th listed compound is found nowhere in 10/681,002 and only the HCl salt is found in 10/915,001. Therefore, since not all of the species claimed are found in each of 10/681,002 and 10/915,001, the claims therefore do not receive the benefit of priority to 10/681,002 or 10/915,001. Applicant additionally argues that the HCl salt in the prior applications provides support according to 35 USC 112 for the compounds and any salt thereof. However, this is not persuasive as the species in applicants' instant claims do not appear in the prior art references as the free form instantly claimed.

In regards to the 35 USC 102 and 103 rejections, Applicants' argue that the rejections should be withdrawn as the instant claims have priority back to US Patent Applications 10/681,002 and 10/915,001. For the reasons discussed above, the instant claims do not receive priority back to the prior applications and the art rejections are therefore maintained.

In regards to the statement supplied by applicants' for the 35 USC 103 rejections of claims 1, 4 and 5, it is noted that the 35 USC 103 rejections are based upon 102(a)

and 102(b), therefore, the statement under 35 USC 103(c) cannot be used to overcome the 103 rejection.

Priority

Applicant has provided a clarification of priority claimed, see the amendment to the specification filed 14 February 2008.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/681,002 and 10/915,001 fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, claims 1, 3, 4 and 5 and newly added claims 11-15 do not find support in the previous applications and therefore only receive the benefit of priority to the date of PCT/FR04/02537 filed 8 October 2004. The subject matter found in claims 1, 3, 4 and 5 and newly added claims 11-15 which does not find support in the previous applications is for example the 6th to 8th and 10th to 28th originally listed compounds of claim 1. These compounds are either found nowhere in the prior application or are found only as an HCl salt. For example, the compound 4-[2-(1-aminocyclopentyl)-1,3-thiazol-4-yl]-2,6-di-tert-butylphenol is found nowhere in Application No. 10/681,002 and only the HCl salt

of 4-[2-(1-aminocyclopentyl)-1,3-thiazol-4-yl]-2,6-di-tert-butylphenol is found in 10/915,001 which does not provide support to a claim to the compound and any salt thereof. Accordingly, claims 1, 3, 4 and 5 and newly added claims 11-15 are not entitled to the benefit of the prior applications 10/681,002 and 10/915,001.

New Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4 and 5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 48-50 and 53-56 of copending Application No. 12/001,439. Although the conflicting claims are not identical, they are not patentably distinct from each other because conflicting claim 48 generically overlaps with applicants instantly claimed invention and provides preferences wherein n is 0-2 in conflicting claim 49 and wherein R1 and R2 are hydrogen (conflicting claim 50). Conflicting claims 53-56 provide the compound and pharmaceutical composition of 4-[2-(aminomethyl)-1,3-thiazol-4-yl]-2,6-di(tert-butyl)-phenol which differs from applicants invention by an aminomethyl instead of an aminoethyl. Additionally, page 99 of the specification provides that the compounds can contain asymmetrical carbon atoms and that the present invention includes the two enantiomeric forms and all combinations of these forms, including the racemic "RS" mixtures. Therefore, the difference between the conflicting claims and applicants' instant claims is a difference in homologs. To those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

New Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 5 and 13-15 rejected under 35 U.S.C. 102(a) or (e) as being anticipated by US 2004/0132788 which discloses compounds such as N-methyl-N-{(1S)-2-methyl-1-[4-(10H-phenoxazin-2-yl)-1,3-thiazol-2-yl]propyl}amine in claim 2.

Maintained Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 02/083656. WO 02/083656 discloses compounds useful for the inhibition of monoamine oxydase for the treatment of diseases such as pain (abstract). For example, WO 02/083656 discloses the last listed compound of claim 7, N-2-dimethyl-1-[4-(10H-phenothiazin-2-yl)-1,3-thiazol-2-yl]propan-1-amine which corresponds to the 2nd listed compound of claim 1 and 4.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3-5 and newly added claims 11-15 are rejected under 35 U.S.C. 102(e) as being anticipated by 7,291,641 which discloses compounds for the treatment of diseases such as pain (abstract). For example, 7,291,641 discloses compounds such as example 496 which is the hydrochloride salt of 4-[2-(1-aminocyclopentyl)-1,3-thiazol-4-yl]-2,6-di-tert-butylphenol and example 486.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2004/0132788 or WO 01/26656.

Determining the scope and contents of the prior art.

US Pre-Grant Publication 2004/0132788 discloses or WO 01/26656 disclose compounds useful for the treatment of diseases such as pain (abstract). For example, the prior art references disclose the compound 4-[2-(aminomethyl)-1,3-thiazol-4-yl]-2,6-di(tert-butyl)phenol (claim 45 US 2004/0132788 or page 237 of WO 01/26656).

Ascertaining the differences between the prior art and the claims at issue

Additionally, page 44 of the Pre-Grant publication or page 71 of the WO disclose that the compounds can contain asymmetrical carbon atoms and that the present invention includes the two enantiomeric forms and all combinations of these forms,

including the racemic "RS" mixtures. Therefore, the difference is a difference in homologs.

Resolving the level of ordinary skill in the pertinent art.

To those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). The motivation would be to prepare additional compounds useful for the treatment of diseases such as pain.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Anderson/
Primary Examiner, AU 1626

21 May 2008

Rebecca Anderson
Primary Examiner
Art Unit 1626, Group 1620
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